

AMENDMENTS TO THE DRAWINGS:

Please delete additional sheets 12-16 of drawings, which were newly presented in the November 19, 2007, Amendment. Drawing sheets 12-16 include FIGs. 17A-25B.

REMARKS/ARGUMENTS

Claims 17-20, 55-66, 141-152 were pending in the present application. Claims 145-146, 148-149 and 151-152 have been cancelled *without prejudice*. Therefore, claims 17-20, 55-66, 141-144, 147 and 150 are now pending in the instant application.

No new matter has been added.

Reexamination of the application and reconsideration of the rejections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Specification/Drawings

Applicants' amendment filed 11/19/07 is objected to under 35 U.S.C. 132(a) as allegedly introducing new matter into the disclosure. Specifically, the examiner cites new drawings submitted with the amendment as containing new matter.

Applicants disagree with the statements made by the examiner regarding the drawings added in the November 19, 2007 Amendment. Furthermore, Applicants maintain that the specification does explicitly disclose non-circular cross-sectional shapes (see, e.g., paragraph [0049] of the specification), and does provide support for the claims that recite non-circular cross-sectional shapes. However, in order to expedite prosecution of the present claims and to bring about a prompt allowance of this application, Applicants in this Amendment are deleting the additional drawing sheets 12-16, illustrating new Figures 17A - 25B, and deleting the corresponding brief descriptions of those additional drawings in paragraphs [0205.1]-[0205.9]. Additionally, in order to render moot the objection to the drawings under 37 C.F.R. § 1.83(a) in the May 18, 2007, final Office Action, Applicants cancel herein dependent claims 145, 146, 148, 149, 151, and 152 without prejudice. Applicants request that this objection be withdrawn.

Claim Rejections - 35 USC § 112

Claims 17-20, 55-66 and 141-152 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. According to the examiner,

“...the written description for Fig. 7A (paragraph [0137] does not provide teaching for the barbed suture having a plane that is perpendicular to the body and cutting transversely through the body and intersection any portion of a barb will not intersect any portion of any other barb on the body” (see Office Action dated April 23, 2008 at page 3, lines 15-18).

Applicants respectfully traverse said rejection.

Applicants respectfully disagree with the Examiner's rejection. Claims 17-20, 55-66 and 141-144, 147 and 150 are directed to the combination of a barbed suture and needle. Applicants note that claims 145-146, 147-149 and 151-152 have been cancelled. In the claims remaining, the barbs are recited as being in a twist cut multiple spiral disposition wherein each successive barb is offset from the previous barb relative to the longitudinal axis of the body such that any plane perpendicular to the body and cutting transversely through the body and intersecting any portion of a barb will not intersect any portion of any other barb on the body. The twist cut multiple spiral method is described

in detail in paragraphs 137-158 of the specification. Applicants contend that the specification clearly describes the twist cut multiple spiral method and that one of ordinary skill in the art, after reading the specification, would readily comprehend said method. Applicants further submit that one of ordinary skill in the art would understand that the twist cut methodology applied to the suture would result in what is shown in Figures 7A-B, and described in independent Claims 17, 18, 141-143. Accordingly, rejection of Claims 17-20, 55-66 and 141-144, 147 and 150 on the basis of 35 U.S.C. §112, first paragraph is unsubstantiated and should be withdrawn.

Claim Rejections - 35 USC § 103

I. Claims 17-20, 141-144, 147 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,123,077 to Alcamo (herein Alcamo) in view of U.S. Patent No. 5,123,911 to Granger (herein Granger), and in further view of U.S. Patent No. 5,269,783 to Sander *et al.* (herein Sander). Applicants respectfully traverse said rejection.

Applicants submit that in the present case, the combination of references cited by the examiner provides no motivation for combination.

Alcamo discloses a variety of sutures that are directed to “roughened” sutures that are sewn, thereby enabling the surgeon “to make a tighter seam”(see, e.g., Alcamo at col. 1, lines 15-25 and col. 2, lines 35-40). Granger teaches a general method for attaching a surgical needle to a standard suture. However, no where does Granger teach or reasonably suggest any advantage associated with a particular needle to suture diameter ratio relating to the efficacy of a barbed suture once used in wound closure. Thus, Applicants submit that the lack of identification of any advantage associated with a particular needle to suture diameter ratio is the result of the absence of any identified advantage when a needle is combined with a barbed suture. It is only with a needle and barbed suture are combined that the needle to suture diameter ratios become relevant as the ratio directly related to the efficacy of the combination. Granger does not teach or suggest the import of the needle to suture diameter ratio. Thus, Granger is inapplicable as a §103 reference in the present context.

Similarly, Sander also fails to remedy the deficiency of Alcamo. Sander teaches a device and method for repairing tissue (see Sander at Abstract). In particular, Sander teaches a device having a pair of needles, wherein each needle has outwardly projecting barbs and wherein the needles are joined by flexible a material, such as a suture (see *Id.* at col. 2, lines 12-26). No where does Sander teach or reasonably suggest a suture comprising barbs as claimed in the present invention. Instead, Sander teaches away from the present invention by teaching a needle comprising barbs. Applicants contend that even if the teaching of Sander were used in connection with Granger and Alcamo, the resulting assembly would be a barbed needle in combination with a standard or “roughened” suture of Alcamo. Sander does not suggest or motivate one of skill in the art to alter a suture with its barbed configuration. Rather, Sander only suggests application of the barbed needle configuration on needles. Sander does not motivate or teach someone of skill in the art to alter a suture with the barb configuration disclosed in Sander. Further, it would not be a predictable variation to incorporate the barbed configuration of Sander into the claimed invention. The resulting hypothetical combined assembly would not resemble the claimed invention.

Applicants note that KSR did not completely reject the teaching, suggestion and motivation standard.¹ The court specifically held that in formulating a rejection using 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person or ordinary skill in the art would have combined the prior art elements in the manner claimed.

Accordingly, in view of the arguments provided herein, rejection of Claims 17-20, 141-144, 147 and 150 under 35 U.S.C. §103(a) as being unpatentable over Alcamo in view of Granger and Sander be withdrawn.

II. Claims 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo in view of Granger and Sander, as applied above, and further in view of U.S. Patent No. 5,931,855 to Buncke.

Applicants respectfully traverse said rejection. Alcamo, Granger and Sander have all been previously described. Bunke discloses barbed sutures that may be made from biodegradable material (see, e.g., Bunke at col. 2, lines 55-57).

As discussed in detail above, the combination of Alcamo/Granger/Sander will not result in the claimed invention. Rather the combination of references at best will result in a hypothetical needle/suture assembly where the needle is barbed in accordance with Sander and the suture used is that taught in Granger or Alcamo. The resulting assembly does not result in the claimed invention. Further, Bunke discloses the use of bio-absorbable sutures. However, if Bunke were included in the Alcamo/Granger/Sander imaginary combined assembly, the resulting device would be a barbed needle in combination with the suture of Alcamo made of a bio-absorbable material. Accordingly, Claims 55-66 are not rendered obvious over Alcamo in view of Granger and Sander, as applied above, and further in view of Buncke.

III. Claims 17-20, 55-66, 141-144, 147 and 150 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke in view of Granger and in further view of Sander *et al.* Applicants respectfully traverse said rejection.

These references have been described above. According to the examiner, Bunke discloses a barbed suture with helically positioned barbs, Granger discloses that it was known to attach sutures to suturing needles, Sander discloses a barbed suture (see Fig. 1) that discloses a barbed suture with successive barbs that are offset from the previous barb relative to the longitudinal axis of the body such that any plane perpendicular to the body and cutting transversely through the body and intersecting any portion of a barb will not intersect any portion of any other barb on the body, and, that a needle to suture ratio of 1.47:1 would be a design choice (see Office Action dated April 23, 2008 at page 7, line 10 through page 9, line 4).

¹ See, e.g., *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories*, 86 USPQ2d 1196 (Fed. Cir. 2008) (ct. held that the TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires. AS KSR requires, those teachings, suggestions or motivations need not be always written references but may be found within the knowledge and creativity of ordinary skill artisans).

Applicants vigorously disagree with the Examiner's rejection. As stated above, Applicants submit that the proposed combination of references does not result in the claimed invention. Rather, the resulting assembly would be a barbed needle of Sander in combination with the sutures disclosed in Alcamo having bio-absorbable qualities. The claims herein are not directed to a barbed needle, but rather define a barbed suture and a surgical needle.

Applicants further submit that the spirality angle was identified by applicants as a further condition, similarly to the needle to suture diameter ratio discussed above, relevant to applicants' claimed embodiments. The spirality angle is described in detail in the description of the invention and in Tables 7A-Y. Table 7Z summarizes the performance of a variety of barbed sutures made in accordance with Tables 7A-Y. As shown in Table 7Z, the sutures that performed best in the two tests were those averaged from Tables N-P and K-M with regard to the chamois cloth pull test, and Tables N-P and Q-S on the straight pull test. In both tests, the range of spirality angle was from 10.8 to 13.8 degrees. Thus, from the data, one of ordinary skill in the art would understand that the spirality angle in this range contributed to the enhanced strength of the sutures in those tables and having the features in accordance with Tables K-S. Applicants submit that the results of testing done, given the skill in the art at the time the invention was made, was not predictable. Rather, the testing was needed by persons skilled in the art to determine what spirality angles would provide an optimum level of strength for the barbed suture of the claimed embodiments. Given the results, and the fact that the results differ between the chamois cloth and straight pull test, it is apparent that the spirality angle for providing optimum strength to the suture is not one of design choice and is not predictable. Accordingly, rejection of Claims 17-20,55-66,141-144,147 and 150 on this basis is unsupported and should be withdrawn.

Applicants further argue that Granger merely discloses a general method of attaching a needle to a standard suture. Granger in no way addresses the issue of needle diameter to suture diameter. Rather Granger addresses the issue of needle shank diameter relative to the diameter of the remainder of the needle body. Granger provides for a needle/suture combination where the diameters of both are the same, i.e. the needle to suture ratio is 1:1. However, Granger does not teach or suggest the use of a needle/barbed suture combination where the needle to suture diameter ratio is 1.47:1. Applicants further note that applicants did indeed note that the 1.47:1 ratio was important. The problem solved by the lower ratio was the increased efficacy of the wound closure, i.e. that it took more strength to tear apart a wound closed with a barbed suture of the claimed invention having a lower needle to suture diameter ratio than it did with the same wound closed with an assembly having a higher ratio. However, Applicants submit that the lower ratio was not an obvious design choice as the types of sutures having varied needle to suture diameter ratios performed differently on rat skin than on chamois cloth. Further, as noted in the application, the ratio may also need to be varied in accordance with its application in the body.

For these reasons, Applicants believe rejection of Claims 17-20,55-66,141-144,147 and 150 is improper and should be withdrawn.

IV. The Examiner has rejected Claims 145,146,148,149,151 and 152 under 35 U.S.C. 103(a) as being unpatentable over Alcamo/Granger/Sander (or Buncke/Granger/Sander), as applied to the claims above, and further in view of U.S. Patent No. 3,918,455 to Coplan. Claims 145,146,148,149,151 and 152 have been cancelled and thus render this rejection moot.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request a notice of allowance to all pending claims. In the event any issues remain, the Examiner is invited to contact the undersigned attorney to resolve the same.

Respectfully submitted,

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